UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 1:01-CV-12257-PBS Sub-Category Case No. 1:08-CV-11200
THIS DOCUMENT RELATES TO: *United States ex rel. Linnette Sun and Greg Hamilton, Relators* *v.* *Baxter Hemoglobin Therapeutics and Baxter International Inc.*	Judge Patti B. Saris

MEMORANDUM IN SUPPORT OF BAXTER INTERNATIONAL INC.'S
MOTION TO DISMISS RELATORS' COMPLAINT

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INTRODUCTION

This Court lacks jurisdiction over Relators' claims that Baxter reported "inflated" AWPs and WACs to First Databank, and thereby violated the False Claims Act ("FCA"). The facts supporting all of these claims were publicly disclosed long before the Complaint was filed, and Relators are not original sources. The Complaint, filed in 2005, contains little detail, but makes essentially the same AWP, WAC, and Best Price allegations that have existed in the public domain for decades. These same allegations were publicly made in a 1984 HHS OIG Report, which was followed by a barrage of OIG, GAO, and Congressional committee reports published during the mid-90s making the same assertions. A 1996 Barron's article, which mentioned Baxter by name, also raised the same allegations. The filing of Relators' Complaint also trailed by several years the "perfect storm" of AWP-related public information described in this Court's prior AWP decisions. Finally, and more critically, the suit was filed long after a multitude of state Attorney General and private actions were initiated in courts around the country in which the very same pricing-related allegations were made against Baxter.

Neither of the Relators can overcome the jurisdictional bar for the FCA claims, because neither is an original source. Greg Hamilton was never a Baxter employee, and has no direct and independent knowledge concerning Baxter. Baxter did not employ Linnette Sun until June 2002, and she was terminated for cause in 2003. While Sun worked at Baxter and may have had access to limited pricing information, the Complaint's allegations were in the public domain long before Sun's period of employment. The Complaint contains none of the additional detail required to establish original source status, nor to satisfy Fed. R. Civ. P. 9(b). Moreover, Relators have not alleged that they disclosed any information to the government before filing suit.

For these same reasons, Relators cannot maintain any claims under the various state false claims or Medicaid fraud statutes included in the Complaint. Indeed, two of these state statutes provide no private right of action at all. In other instances, Relators' claims do not meet state statutory requirements and/or those states have already filed and settled similar cases against Baxter.

Finally, Relators' Stark Act claim must be dismissed for lack of standing and failure to state a cause of action.

At the end of the day, only five claims[1] by Relator Sun should survive this Motion to Dismiss. These employment-related claims do not share a "common question[] of fact" with the AWP claims being adjudicated in this Court, and thus should be transferred back to the District of Colorado for disposition. *See* 28 U.S.C. § 1407(a).

BACKGROUND

Relators Hamilton and Sun filed their original complaint against Baxter International Inc. ("Baxter") and a now defunct former affiliate, Baxter Hemoglobin Therapeutics,[2] under seal in the United States District Court for the District of Colorado on April 22, 2005 (Civ. A. No. 05-CV-00736). The Amended Complaint for Damages Under the Federal and Various State False Claims Acts (cited herein as "Complaint") was filed under seal on June 14, 2005. The Complaint was unsealed on January 15, 2008, following the Department of Justice's decision not

[1] Baxter has not moved to dismiss Counts IV (Retaliation in Violation of 31 U.S.C. § 3730(h)), V (Retaliation in Violation of California Government Code § 12653), VI (Retaliation in Violation of California Public Policy), XXII (Discrimination Under the California Fair Employment and Housing Act), or XXIII (Harassment Under the California Fair Employment Housing Act).

[2] Neither Baxter International Inc. nor Baxter Hemoglobin Therapeutics is an appropriate defendant in this case. Baxter Healthcare Corporation is the corporate entity that sells, distributes, and prices Baxter drugs and therapies in the United States. Moreover, neither Baxter International Inc. nor Baxter Hemoglobin Therapeutics employed Sun.

to intervene in the case.[3] On July 15, 2008, the Judicial Panel on Multi-District Litigation transferred the case to this Court.

ARGUMENT

I. THE FCA CLAIMS MUST BE DISMISSED FOR LACK OF SUBJECT MATTER JURISDICTION AND FAILURE TO PLEAD WITH REQUISITE PARTICULARITY.

No court has jurisdiction over a *qui tam* action when that action is "based upon the public disclosure of allegations or transactions . . . unless . . . the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A);[4] *United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 90-91 (D. Mass. 2001). This jurisdictional requirement presents a threshold question for the Court, and Relators bear the heavy burden of proving jurisdiction under the FCA. *United States ex rel. West v. Ortho-McNeil Pharm., Inc. (In re Pharm. Indus. Average Wholesale Price Litig.)*, 538 F. Supp. 2d 367, 375 (D. Mass. 2008) (citing *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 466-70 (2007); *United States ex rel. Rost v. Pfizer*, 507 F.3d 720, 727 (1st Cir. 2007) (abrogation recognized by *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40 (1st Cir. 2009))). Deciding whether a claim is precluded by the public disclosure bar requires a multi-step inquiry:

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[3] To date, no state has intervened in the case. Baxter is aware that Nevada and California specifically declined to intervene. *See* Notice of Non-Intervention by State of Nevada, Sun Sub-Docket, Case No. 1:08-CV-11200, No. 57 (referencing Colorado Docket No. 29) (Jan. 29, 2007); Notice of Non-Intervention by the State of California, Sun Sub-Docket, Case No. 1:08-CV-11200, No. 57 (referencing Colorado Docket No. 45) (May 23, 2008). The time has long passed for any of the remaining states to join the case.

[4] The state and D.C. statutes under which Relators assert claims are nearly identical in all pertinent respects to the FCA. *See* Ark. Code Ann. § 20-77-901 *et seq.*; Cal. Gov't Code § 12650 *et seq.*; Del. Code Ann. tit. 6, § 1201 *et seq.*; D.C. Code § 2-308.03 *et seq.*; Fla. Stat. § 68.081 *et seq.*; Haw. Rev. Stat. § 661-22 *et seq.*; 740 Ill. Comp. Stat. 175/1 *et seq.*; La. Rev. Stat. Ann. § 46:439.1 *et seq.*; Mass. Gen. Laws ch. 12, § 5(A) *et seq.*; Nev. Rev. Stat. § 357.010 *et seq.*; N.M. Stat. § 27-14-1 *et seq.*; Tenn. Code Ann. § 71-5-181 *et seq.*; Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; Utah Code Ann. § 26-20-1 *et seq.*; Va. Code Ann. § 8.01-216.1 *et seq.* For ease of reference, we cite only to the relevant provisions of the FCA herein unless a particular state statute has different or additional requirements.

> "(1) whether there has been public disclosure of the allegations or transactions in the relator's complaint; (2) if so, whether the public disclosure occurred in the manner specified in the statute; (3) if so, whether the relator's suit is 'based upon' those publicly disclosed allegations or transactions; and (4) if the answers to these questions are in the affirmative, whether the relator falls within the 'original source' exception as defined in § 3730(e)(4)(B)."

West, 538 F. Supp. 2d at 376 (quoting *Rost*, 507 F.3d at 728). As described below, claims of inflated AWPs and WACs and misreported Best Prices (collectively referred to herein as "Pricing Schemes") were made and publicly circulated against Baxter years before Relators filed this Complaint. Relators do not qualify as original sources, and therefore the FCA claims must be dismissed. In addition, or in the alternative, the FCA claims must be dismissed because they are not pled with the necessary particularity.

A. The Allegations In The Complaint Were Publicly Disclosed Before Relators Filed Their Lawsuit In 2005.

The public disclosure bar was added to the FCA by Congress in 1986 to "'discourag[e] "parasitic" or "free-loading" qui tam suits while also encouraging productive private enforcement suits.'" *West*, 538 F. Supp. 2d at 376 (quoting *Rost*, 507 F.3d at 727). The bar applies to "allegations or transactions" made in a "criminal, civil, or administrative hearing, in a congressional, administrative, or Government [Accountability] Office report, hearing, audit, or investigation, or from the news media," unless the person bringing the action is an original source of the information. 31 U.S.C. § 3730(e)(4)(A). Each of the sources cited below qualifies as a public disclosure.

1. Previously Filed Lawsuits Revealed The Pricing Schemes Relators Purport To Uncover.

No fewer than 38 AWP complaints,[5] all alleging essentially the same AWP/WAC inflation scheme, had been filed against Baxter before Relators filed this 2005 lawsuit.[6] The Master Consolidated Class Action Complaint ("MCC") was filed nearly three years before Relators filed this suit. *See* MDL 1456, Docket No. 148 (Sept. 6, 2002). In the MCC, Plaintiffs specifically alleged that Baxter "engaged in an ongoing deliberate scheme to inflate AWPs in order to increase the market share of its products." *Id.* ¶ 212; *see also id.* ¶¶ 213-219. In 2002, the State of Nevada also filed a suit alleging that Baxter caused to be reported false or inflated AWPs. *See* Exhibit B (*Nevada v. Abbott Labs., Inc., et al.*, Case No. 02-00260, Department No. 8 (2d Jud. Dist. Ct., County of Washoe, Jan. 17, 2002)) ¶¶ 1-11, 25, 60(j), 61. All of the other prior complaints make similar allegations regarding AWP and/or WAC inflation.

The Best Price allegations in Relators' Complaint ¶¶ 49-51, 53-61, 85-88 (Count III), also were asserted in earlier lawsuits against Baxter. The Nevada Complaint, for example, charged Baxter with misrepresenting its Best Prices. Exhibit B ¶¶ 137-152. So, too, did other state Attorney General and New York County lawsuits. *See, e.g.*, Exhibit C (*Montana ex rel. Mike McGrath, Attorney General v. Abbott Labs., Inc., et al.*, Case No. ADV-2002-2155 (1st Jud. Dist. Ct., Feb. 25, 2002)) ¶¶ 90-93, 125-131; Exhibit D (*County of Nassau v. Abbott Labs et al.*, Case No. CV 04-5126 (E.D.N.Y. Nov. 24, 2004)) ¶¶ 92-99, 133, 185, 411-429. Moreover, a number of the complaints refer to alleged improprieties concerning volume discounts, similar to

[5] Before this Complaint was filed, Baxter was named as a defendant in 11 private class action cases that were consolidated in the September 6, 2002 Master Consolidated Complaint in MDL 1456; in 11 state cases; and in 16 New York County cases. *See* Exhibit A to the Declaration of Ruchi Jain in Support of Baxter International Inc.'s Motion to Dismiss Relators' Complaint (List of Prior Cases). Other exhibits to this Declaration will be referred to herein as simply "Exhibit ___."

[6] This Court has previously determined that civil complaints qualify as public disclosures under the FCA. *West*, 538 F. Supp. 2d at 377.

the Best Price allegations related to "Volume Committed Contracts" in Relators' Complaint ¶ 51. *See, e.g.*, MCC ¶ 165 (referring to "volume discounts, rebates, off-invoice pricing, free goods," etc.); Exhibit D (Nassau County Complaint) ¶¶ 95, 96 (discussing alleged improprieties associated with volume discounts, wholesaler chargebacks, and volume-based rebates).

2. The Pricing Schemes Alleged In Relators' Complaint Were Extensively Covered In Government Reports And By The News Media.

This Court has ruled that "[b]y the mid-1990's, information about the existence of mega-spreads began to seep into the marketplace," *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 40 (D. Mass. 2007); that by August 1997, information was widely available demonstrating that AWP-based reimbursement did not accurately reflect acquisition costs, *id.* at 78-79; and, that "[b]y 2001, there was a perfect storm of information that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General," *id.* at 41. This information included both government reports and news media coverage.

a. Government Reports

Placing to one side general reports and statements made well before the filing of Relators' Complaint,[7] numerous public reports specifically referred to alleged "spreads" for Baxter drugs and therapies. For example:

[7] *See*, for example:

- A 1984 HHS OIG Report, finding that AWPs are not adequate estimates of the prices providers pay for drugs because "[w]ithin the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price." Exhibit E at 3.
- A 1996 HHS OIG Report on physician-administered drugs, again concluding that AWP is not a reliable indicator of the cost of drugs to providers. Exhibit F at ii, 8.
- Numerous other HHS OIG reports dating back to 1992, discussing the difference between AWP and the actual prices paid by purchasers, as catalogued in the report of this Court's appointed expert, Dr. Ernst R. Berndt. Exhibit G (Attachment B to the February 9, 2005 Report of Independent Expert Professor Ernst R. Berndt, MDL 1456, Docket No. 1384 (June 11, 2007)).

- A December 1997 HHS OIG report, *Excessive Medicare Payments for Prescription Drugs*, which compared Medicare drug expenditures to purchases from wholesalers and group purchasing organizations for select drugs, including IVIG (intravenous immune globulin), a category into which Gammagard S/D falls.[8] The report found that in 1995 and 1996, the average Medicare allowed amount for this product (J1561) was approximately $42, but the actual average wholesale price was in the $16 range. Exhibit I at Appendix B-2 and B-3.

- In 2000, the Department of Justice and National Association of Medicaid Fraud Control Units provided an alternative source of AWP data, so-called DOJ AWPs, to First DataBank, which in turn provided these to state Medicaid programs. Exhibit J at 1. DOJ AWPs were provided for Baxter therapies Gammagard and Recombinate. *Id.* at 9, 18. These AWPs were significantly lower than had previously been reported by First DataBank.

- A September 25, 2000 letter from Congressman Bliley, Chair of the House Commerce Committee, to Nancy-Ann Min DeParle, HCFA Administrator, discussing AWP inflation, Exhibit K at 1, including Bayer documents addressing Baxter's AWPs for Recombinate, *id.* at 7 and Attachment 6 (unnumbered page 3). The letter cited, as one example of marketing the spread, Baxter documents related to the drug Gammagard. *Id.* at 7-8, Attachment 6 (unnumbered pages 4-7) and Attachment 7. One of these Baxter documents regarding Gammagard is quoted in the MCC. MCC ¶ 214 (citing Bliley Sept. 25, 2000 letter).

- A January 2003 GAO Report entitled *Medicare: Payment for Blood Clotting Factor Exceeds Providers' Acquisition Cost*, reporting that hemophilia treatment centers and homecare companies obtain prices from manufacturers of blood clotting factors[9] that are significantly below AWPs. Exhibit L at 3, 10.

These are precisely the types of public reports that qualify as "public disclosure[s]" within the meaning of the 1986 Amendments to the FCA. 31 U.S.C. § 3730(e)(4)(A); *see also United States ex rel. Waris v. Staff Builders, Inc.*, No. 96-1969, 1999 U.S. Dist. LEXIS 15247, at *11 (E.D. Pa. Oct. 4, 1999) (publicly available reports prepared by government agencies are

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[8] *See* Exhibit H (Declaration of Michael Bradley) ¶ 5. In determining whether or not subject matter jurisdiction exists, the Court may consider documents beyond the Complaint. *See, e.g., United States ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 348 (4th Cir. 2009) (citing *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 514 (2006) (to resolve jurisdictional facts in dispute, a court may consider evidence outside the pleadings, such as affidavits)).

[9] Of the ten drugs referenced by Relators in Complaint ¶ 20, most are blood clotting factors (hemophilia therapies). These are Advate, Bebulin, Feiba H (*sic*), HemophilM (*sic*), Propelex (*sic*), Propelex LT (*sic*), and Recombinate. *See* Exhibit H (Declaration of Michael Bradley) ¶ 6; *see also infra* note 14 for explanations of the "*sic*" references and additional information regarding Relators' Complaint ¶ 20.

"paradigmatic example[s]" of public disclosures under § 3730(e)(4)(A)). All of these reports pre-date Relators' Complaint by years.

Indeed, nearly two years before Relators filed their Complaint, in June 2003, the Medicare Modernization Act was introduced in Congress. As this Court noted, "[t]he statute and the legislative history [of the Medicare Modernization Act] indicate that by 2003, [AWP] had become a term of art. At that point, Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace." *In re Pharm. Indus. Average Wholesale Price Litig. (Track One)*, 460 F. Supp. 2d 277, 288 (D. Mass. 2006).

b. News Media

News media coverage also constitutes public disclosure. *See United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y.), *aff'd*, 53 F. App'x 153 (2d Cir. 2002). Among the public disclosures in the news media that are relevant to this case are:

- A June 10, 1996 Barron's article, *Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals?*, describing AWP as "Ain't What's Paid" and concluding that providers pay as much as 60% to 90% below AWP. Exhibit M at 2. This article specifically mentions Baxter by name, listing it as "[a]mong the publicly traded companies that could be affected" by this report, *id.*, and adding "[t]he pricing unreality is even worse for intravenous nutritionals and solutions, a category dominated by [Abbott and Baxter]. Catalog wholesale prices for these items are, on average, 80% to 93% below those companies' AWPs," *id.* at 3.

- An April 2000 Marketing Research Bureau[10] report, *Survey on Hemophilia Care & Price Monitoring United States: Wave # 10*, discussing the "minimum acquisition prices" (actually Public Health Service ("PHS") prices) for which hemophilia therapies can be purchased, as well as the cost of these therapies to patients and insurers. Exhibit N. For example, the PHS price for Recombinate is

[10] Marketing Research Bureau is a publisher of research studies concerning the pharmaceutical industry. At least two federal courts have found that disclosure of information in such highly technical trade journals falls within the "news media" disclosure bar. *See Alcohol Found.*, 186 F. Supp. 2d at 463; *United States ex rel. Radcliffe v. Purdue Pharma L.P.*, 582 F. Supp. 2d 766, 770-71 (W.D. Va. 2008). Relators admit that they consulted Marketing Research Bureau reports in preparing the Complaint. Complaint ¶ 29; *see also infra* p. 12-13.

$0.615, *id.* at 63, 81; the PHS price for Proplex T is $0.167, *id.* at 63; and the PHS price for Feiba VH is $0.73, *id.* at 63, 81. According to the report, the "acquisition prices" for Recombinate for January 2000 ranged from $0.62 to $0.88, *id.* at 25, and the "price to patients" for Recombinate ranged from $0.82 to $0.87, *id.* at 62 and $0.74 to $1.00, *id*. at 30. This report also listed published AWPs. For example, for January 2000, the AWP for Recombinate was $1.28, for Hemofil M was $0.95, for Proplex T was $0.33, for Bebulin VH was $0.55, and for Feiba VH was $1.50. *Id.* at 51.

- News media coverage of the original AWP lawsuits filed in 2001 and 2002 that were consolidated into the MDL. Exhibit O.

B. Relators' Allegations Are "Based Upon" The Prior Public Disclosures.

The jurisdictional bar applies when the *qui tam* suit is "based upon" public disclosures. 31 U.S.C. § 3730(e)(4)(A). The majority view, endorsed by this Court, is that a *qui tam* suit is "'based upon' a public disclosure when the allegations in the relator's complaint are similar to, supported by, or 'the same as those that have been publicly disclosed . . . *regardless of where the relator obtained his information.*'" *West*, 538 F. Supp. 2d at 377 (emphasis and alteration in original) (quoting *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1992)). Relators' Pricing Schemes here are undeniably "similar to" (if not "the same as") those in the public disclosures.

Where, as here, a broad "scheme" has already been publicly disclosed, even if a relator contributed specific details of that scheme, the relator's suit would *still* be based on the public disclosure: "it [is] enough that the public disclosure outlined the general fraudulent scheme – the relator's suit was still based on the public disclosure even though it added the who, when, and where of one specific instance of a fraud that had been generally described in the public disclosure." *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 49 (D.D.C. 2007) (citing *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 683 (D.C. Cir. 1997) ("the jurisdictional bar . . . encompass[es] situations in which the relator's complaint repeats what the public already knows")).

In *United States ex rel. Springfield Terminal Railway Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994), the D.C. Circuit established a test to determine whether allegations are "based upon" public disclosures: "[I]f X + Y = Z, Z represents the *allegation* of fraud and X and Y represent its essential elements. In order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z." Stated in terms of this paradigm, the public disclosures discussed above identified an allegedly improper spread between Baxter's reported AWP (the "X") and its actual prices (the "Y") and described the fraudulent act of marketing the spread (the "Z"). *Id.*; *see also West*, 538 F. Supp. 2d at 383-85. The Complaint is "based upon" these disclosures.

C. Relators Are Not Original Sources.

Because the Pricing Schemes are based upon public disclosures, the Court has subject matter jurisdiction over the FCA claims only if Relators can prove that they are "original sources" of the information. 31 U.S.C. § 3730(e)(4)(A). An original source is defined as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B). Relators do not meet either of these requirements.

1. Relators Did Not Provide Their Information To The Federal Government Before Filing This Lawsuit.

As this Court has indicated, part of the "original source" inquiry requires a determination that the relator voluntarily provided the pertinent information to government authorities before initiating a *qui tam* case. *West*, 538 F. Supp. 2d at 384 (citing 31 U.S.C. § 3730(e)(4)(B)). Relators have offered no evidence that they can satisfy this requirement; nowhere in the Complaint do Relators claim to have provided any information about the alleged Pricing Schemes and Stark Act violations to any federal government authority prior to filing their

qui tam suit. Relators must provide such proof in order for this case to go forward. *See Rockwell Int'l*, 549 U.S. at 466 (noting that plaintiff bears the burden of proving that he informed the proper authorities before filing); *see also Grynberg ex rel. United States v. Pac. Gas & Elec. Co. (In re Natural Gas Royalties)*, 562 F.3d 1032, 1044 (10th Cir. 2009); *United States ex rel. Settlemire v. District of Columbia*, 198 F.3d 913, 920 (D.C. Cir. 1999). In the absence of new information regarding Relators' pre-filing disclosures, Relators cannot be original sources.[11]

2. Relators Lack Direct And Independent Knowledge Of Any Relevant Information.

As reflected in their reliance on the pre-existing public record in the Complaint, Relators also lack the required "direct and independent" knowledge that Baxter reported false or inflated AWPs/WACs and/or inaccurate Best Prices. "Direct and independent knowledge must be something more than 'secondhand information' or 'collateral research and investigations.'" *United States ex rel. Montgomery v. St. Edward Mercy Med. Ctr.*, No. 4:05-CV-00899 GTE, 2007 WL 2904111, at *10 (E.D. Ark. Sept. 28, 2007) (quoting *United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 703 (8th Cir. 1995)). Direct knowledge is "'firsthand knowledge of the alleged fraud'" obtained through the relator's "'own labor unmediated by anything else.'" *West*, 538 F. Supp. 2d at 384 (quoting *United States ex rel. Aflatooni v. Kitsap Physicians Servs.*, 163 F.3d 516, 525 (9th Cir. 1999)). Under this standard, neither Hamilton nor Sun can establish that he or she is an "original source."

a. Hamilton

Hamilton was never employed by, nor had any association with, Baxter, and had absolutely no opportunity to gain firsthand knowledge about Baxter's practices. In fact, Hamilton fails to allege a single piece of direct and independent knowledge regarding Baxter in

[11] As discussed *infra* p. 18, because Relators also apparently did not provide information to pertinent state authorities prior to filing suit, the state false claims and Medicaid fraud claims must be dismissed as well.

the Complaint. Any information in the Complaint contributed by him was apparently the product of his reviewing publicly available information as a "pricing and reimbursement specialist."[12] *See* Complaint ¶ 8; *id.* ("He is aware of the pricing structure Baxter used, specifically, the correspondence between Baxter and FDB regarding Baxter's reporting of the improper WAC."); *see id.* ¶ 29 (referring to a public research report). Because Hamilton's role in the Complaint was merely to provide speculative or secondhand information about Baxter gleaned from the public record, he cannot qualify as an "original source" under the FCA.

Hamilton's research and supposed expertise might have enabled him to contribute to the Complaint by describing the way biologicals are sold through wholesalers and other distributors, and how price reporting works in general, *see id.* ¶¶ 27-40, but his collateral research and investigation is insufficient for subject matter jurisdiction purposes. In fact, Hamilton concedes that the source of the information for his contributions to the Complaint is his own review of public information. *See, e.g., id*. ¶¶ 8, 29. This review of public information obviously does not constitute "direct and independent" knowledge as required by *Rockwell International*.

One example of how the Complaint was culled together from public documents can be seen in a comparison between the list of wholesalers referred to in Complaint ¶ 28 and a list of wholesalers in the Marketing Research Bureau report cited in Complaint ¶ 29, *The Plasma Fractions Market in the United States 2001*. The Marketing Research Bureau report notes that

[12] Hamilton has long been involved in pharmaceutical lawsuits, some of which have included AWP and Best Price claims. He was retained by Relators' counsel here, Mr. Kleiman, as a consulting expert in a Best Price case, *Nevada ex rel. Steinke v. Merck & Co.*, No. CV-N-05-322-HDM (D. Nev. 2005); was hired by plaintiffs as a potential expert on pharmaceutical marketing in *Strong v. Merck & Co.*, No. CV 2005-053195 (Ariz. Sup. Ct. 2008); and was a proposed rebuttal witness for plaintiffs in an AWP case, *Kentucky ex rel. Conway v. Alpharma USPD, Inc., et al.*, No. 04-CI-1487 (Ky. Cir. Ct. 2009).

its list is "in no particular order," *see* Exhibit P at 169, yet Relators repeat this non-alphabetical, random order exactly in beginning their list at Complaint ¶ 28.

Similarly, Relators allege that the reported AWP for Recombinate is $1.30 per unit and that it "has been sold to providers for $0.89 (or even less)." Complaint ¶ 36. They cite no direct and independent knowledge as the source of this information. Nowhere in ¶ 36 or the preceding paragraphs do Relators state or even intimate that this was information Sun learned during the course of her employment, as they do elsewhere in the Complaint. *Compare* Complaint ¶ 36 *with id.* ¶¶ 41-48. This information likely came from available public sources, such as First Databank's publication (to which Hamilton would have access as a "pricing and reimbursement specialist") and public reports such as Marketing Research Bureau reports. The Marketing Research Bureau report *Survey on Hemophilia Care & Price Monitoring United States: Wave # 10*, for example, includes "acquisition prices" of Recombinate for January 2000 ranging from $0.62 to $0.88, Exhibit N at 25, and "price to patients" of Recombinate of $0.82 to $0.87, *id*. at 62. This report also listed the January 2000 AWP for Recombinate as $1.28. *Id*. at 51. Recombinate also was a covered drug in the MCC, as well as the Nevada and Montana Complaints, which were filed years before the instant suit. *See* MCC ¶ 71; Exhibit B (Nevada Complaint) ¶ 61; Exhibit C (Montana Complaint) ¶ 82.

b. Sun

Although Sun was at least employed by Baxter, Sun also does not qualify as an "original source," because she does not possess the required direct and independent knowledge to support the Complaint's allegations. To begin with, Sun did not even start to work for Baxter until well after the public disclosures and "perfect storm" of information underlying the AWP litigation. Sun started working for Baxter on June 24, 2002. Her employment ended on July 22,

2003.[13] Complaint ¶ 7. "Direct and independent knowledge" is limited to the period of employment; a relator cannot have direct knowledge of an employer's misconduct that allegedly occurs before or after the relator is employed by the company. *See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 551 F. Supp. 2d 100, 109 (D. Mass. 2008), *aff'd in part, rev'd in part*, No. 08-1409, 2009 WL 2450716 (1st Cir. Aug. 12, 2009) (asserting that a relator's direct knowledge of his employer's activities "only extends to the time he was employed by the company"); *cf. Rockwell Int'l*, 549 U.S. at 475 (relator's prediction of what would occur after he left a company's employ is not knowledge).

Sun's direct knowledge of Baxter's alleged Pricing Schemes is also limited to what she "'saw . . . with [her] own eyes.'" *Barth*, 44 F.3d at 703 (citation omitted). But Sun admits that she obtained some of her "knowledge" from public sources. *See* Complaint ¶ 64 (Sun obtained materials related to the TAP Lupron and AstraZeneca Zoladex cases); *id.* ¶ 45 (referencing Sun's "research"). The Complaint contains scant detail as to what Sun supposedly unearthed about the alleged Pricing Schemes. For example, Sun vaguely refers to "internal documents she studied while working at Baxter, and discussions . . . with pricing specialists and senior marketing executives." *Id.* ¶ 48. She also claims Baxter employees told her that "Baxter could get into trouble" or that "Baxter management would go to jail" were certain information discovered. *Id.* ¶¶ 43, 46. Such claims, even if they were true, would be irrelevant. Sun cannot be an original source based only on vague accusations of wrongdoing.

Relators have alleged Pricing Schemes, but they have not supported them with original, firsthand evidence. For example, with respect to the Best Price claim, Sun claims only that she *once* saw what she calls an "illegal" "Volume Committed Contract[]." *Id.* ¶ 51. Sun

[13] Relators mention an alleged conversation between Sun and a Baxter employee before Sun came to work for the company. *See* Complaint ¶ 38 ("[i]n approximately October 2001"). Baxter assumes this is simply a typographical error.

claims to have only briefly glimpsed this document during a meeting. *Id.* She does not claim to have any direct (or indirect) knowledge of how this one contract she saw was or was not accounted for in Baxter's Best Price calculations. Indeed, nowhere in the Complaint does Sun allege that she was involved with, or even aware of, the means by which Baxter calculated and reported Best Prices.

With respect to the AWP/WAC inflation allegations, Sun provides only one specific. She alleges that at some unidentified point in time, "Baxter decided" to sell Advate for $0.99 but to report an AWP of $1.60. *Id.* ¶ 43. Notably, Relators do not assert that $1.60 was the actual reported AWP or name any customers who purchased the drug for $0.99. In fact, Baxter never reported, nor did any publisher ever publish, an AWP of $1.60 for Advate. Exhibit H (Declaration of Michael Bradley) ¶ 8. In any event, furnishing this one detail is insufficient to establish Sun as an original source. *See infra* §I(D).

D. The FCA And Stark Act Counts In The Complaint Must Be Dismissed For Failure To Allege Fraud With Particularity As Required By Fed. R. Civ. P. 9(b).

Fed. R. Civ. P. 9(b) applies to FCA cases. *See, e.g., California ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Abbott Labs., Inc. (In re Pharm. Indus. Average Wholesale Price Litig.)*, 478 F. Supp. 2d 164, 171 (D. Mass. 2007) ("*Qui tam* actions under the federal False Claims Act must comply with Fed. R. Civ. P. 9(b)." (citing *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004))). "To pass Rule 9(b) muster, [an FCA] complaint must plead with particularity the time, place and contents of the false representations as well as the identity of the person making the false representations and what he obtained with them." *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001).

Because they lack direct and independent knowledge, it is not surprising that Relators also have failed to allege the FCA violations with the particularity required under Rule 9(b). The Complaint here is filled with vague allegations of Pricing Schemes, yet is utterly lacking in detail. *See supra* § I(C)(2). Compare, for example, the allegations in *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, No. 08-1409, 2009 WL 2450716, at *15 (1st Cir. Aug. 12, 2009), where, for the FCA claims that were permitted to go forward, relator Duxbury provided specifics that included "the dates and amounts of the false claims filed by [medical providers] with the Medicare program." "In particular, Duxbury . . . identified, as to each of the eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and the when), and the filing of the false claims themselves." *Id.* at *16. Even with these specifics, the First Circuit deemed the Rule 9(b) analysis "a close call." *Id.* In contrast, Relators here do not provide any concrete details about, for example, which provider filed a false claim based on an inflated AWP or WAC (who), or where or when this occurred, nor do they offer any information about the filing of the alleged false claims. Relators only provide the "what," the alleged spreads, and then only for two drugs — Recombinate (Complaint ¶ 36) and Advate (Complaint ¶ 43), *see also supra* § I(C)(2). Relators AWP and WAC inflation claims cannot survive a Rule 9(b) analysis based on this limited information.

Relators similarly have failed to establish the existence of any Best Price "violation" for any drug named in the Complaint. Nowhere do Relators allege what false Best Prices Baxter reported, what those Best Prices should have been, or what drugs were part of the alleged scheme. Instead, Relators simply speculate that because Baxter gave volume-based discounts to its customers, it must not have calculated or reported Best Prices correctly. *See* Complaint ¶ 85; *see also id.* ¶¶ 49-51, 53-61, 84, 86-88. Such bare accusations, made without "direct and

independent" information that discounts and rebates were not included in Best Price reporting, cannot sustain a fraud-based claim under Rule 9(b). *See West*, 538 F. Supp. 2d at 385.

In similar fashion, Relators identify ten drugs as part of the alleged Pricing Schemes, but provide no specifics at all about eight of the drugs, mentioning them only once in the Complaint, in an introductory paragraph. *See* Complaint ¶ 20.[14] Likewise, Relators make passing reference to a number of federal programs, including the Railroad Retirement Medicare Program, Indian Health Service, Federal Employee Health Benefit Plans, Tri-Care, the Veteran's Administration, and the Section 340B Program, *id.* ¶¶ 14-19, but make no real connection between any of these programs and the alleged violations.

In short, Relators' allegations concerning the Pricing Schemes are grossly insufficient under Rule 9(b), and therefore Counts I and III must be dismissed.[15]

Finally, Relators allege no specifics concerning the Stark Act claim (Count II). This Count therefore must be dismissed under Rule 9(b) as well. *See United States ex rel. Frazier v. IASIS Healthcare Corp.*, 554 F. Supp. 2d 966, 973 (D. Ariz. 2008) (applying Rule 9(b) to Stark Act claims).

II. RELATORS' STATE CLAIMS MUST BE DISMISSED.

Relators seek recovery under false claims and Medicaid fraud statutes of Arkansas, California, Delaware, the District of Columbia, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Mexico, Tennessee, Texas, Utah, and Virginia. *See* Complaint

[14] The eight drugs named in Complaint ¶ 20 for which no specifics are alleged are: Aralast, Albumin, Bebulin, FeibaH (*sic*), Gammagard S/D, HemophilM (*sic*), Propelex (*sic*), and Propelex LT (*sic*). Baxter makes no drug called "FeibaH," although it does sell a product called Feiba VH. *See* Exhibit H (Declaration of Michael Bradley) ¶¶ 6-7. Similarly, Baxter does not sell any product called "Propelex" or "Propelex LT," although it manufactures and sells Proplex T. *Id.* Finally, Baxter sells Hemofil M, not HemophilM. *Id.*

[15] Indeed, Relators' Complaint is in many respects insufficient even under the lesser pleading standards of Fed. R. Civ. P. 8. *See generally Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009).

¶¶ 1-6, 20-48, 65-71, 105-252 (Counts VII-XXI). For the following reasons, these claims also must be dismissed.

A. Dismissal Of Federal FCA Claims Requires Dismissal Of Parallel State Claims As Well, Because The State Statutes Under Which Relators Seek Recovery Mirror, Or Are Even More Restrictive Than, The Federal FCA.

The various state false claims and Medicaid fraud statutes closely parallel the federal FCA statute. *See supra* note 4. It follows that if this Court finds that the allegations at the heart of the federal FCA claims were publicly disclosed, that Sun and Hamilton were not original sources, or that the FCA claims were not pled with requisite particularity, then these findings would likewise apply to the state claims. Thus, Counts VII through XXI must be dismissed.

In addition, all the state statutes at issue (except for Arkansas and Utah, addressed *infra*) require that Relators voluntarily provide information related to the alleged false claims to a specified individual or entity within the state government before filing. *See* Cal. Gov't Code § 12652(d)(3)(B); Del. Code Ann. tit. 6, § 1206(c); D.C. Code § 2-308.15(c)(2)(B); Fla. Stat. § 68.087(3); Haw. Rev. Stat. § 661-28; 740 Ill. Comp. Stat. 175/4(e)(4)(B); La. Rev. Stat. Ann. § 46:439.1(B)(2); Mass. Gen. Laws ch. 12, § 5(A); Nev. Rev. Stat. § 357.100(2)(b); N.M. Stat. § 27-14-10(C); Tenn. Code Ann. § 71-5-183(e)(2)(B); Tex. Hum. Res. Code Ann. § 36.113(b); Va. Code Ann. § 8.01-216.8. Given the absence of such proof here, these claims must be dismissed on this ground alone.

As an additional hurdle for potential *qui tam* relators, the false claims acts of California, Nevada, the District of Columbia, and Hawaii require that a relator whose allegations are based upon public disclosures prove that he or she is the very person "whose information provided the basis or catalyst for the investigation, hearing, audit or report that led to the public disclosure" in order to qualify as an original source. Cal. Gov't Code § 12652(d)(3)(B) (California); Nev. Rev. Stat. § 357.100(2) (Nevada); D.C. Code § 2-308.15(b)(2)(B) (District of

Columbia); Haw. Rev. Stat. § 661-28 (Hawaii); *see also West*, 538 F. Supp. 2d at 389-90. Relators have not made, and cannot make, this claim. This provides a separate and independent basis for dismissal of Counts VIII (California), XVI (Nevada), XVII (District of Columbia), and XI (Hawaii).

The Massachusetts False Claims Act includes a further restriction – that no court shall have jurisdiction over a Massachusetts false claims action "brought by a person who knew or had reason to know that the attorney general, the state auditor or the inspector general already had knowledge of the situation." Mass. Gen. Laws ch. 12, § 5(G)(3); *see Scannell v. Attorney General*, 872 N.E.2d 1136, 1139 (Mass. App. Ct. 2007). Given the extensive, nationwide scope of the Master Consolidated Class Action, and given that Massachusetts itself filed AWP actions as early as 2003,[16] Relators had reason to know that Massachusetts officials already had knowledge of the alleged wrongdoing. This provides a separate ground for dismissal of this claim (Count VII).

B. Arkansas And Utah Do Not Permit Private Rights Of Action Under Their State False Claims Acts.

Relators' claim on behalf of Arkansas is barred because there is no private right of action under the Arkansas False Claims Act. *See* Ark. Code Ann. §§ 20-77-902, 908(c). Similarly, in Utah, only the state Attorney General may bring a False Claims Act suit; the Utah False Claims Act does not include a *qui tam* provision allowing for a private right of action. *See* Utah Code Ann. § 26-20-13. Thus, the Arkansas and Utah claims (Counts XX and XXI) must be dismissed.

[16] *See, e.g.*, *Massachusetts v. Mylan Labs., Inc.*, No. 03-11865-PBS (D. Mass. complaint filed Sept. 25, 2003). Baxter has not been named as a defendant in any of the Massachusetts actions.

C. The California, Hawaii, Illinois, Nevada, And Texas Claims Must Be Dismissed For The Additional Reason That Those States Pursued Their Own AWP/WAC Lawsuits Against Baxter And Settled With Baxter.

Under various statutory "first to file" provisions preventing duplicative suits, as well as the doctrine of accord and satisfaction, Relators' claims concerning California, Hawaii, Illinois, Nevada, and Texas must be dismissed. Because Baxter has already settled overlapping suits with these states, Relators cannot now go forward with similar claims.

1. California (Count VIII)

Under the California False Claims Act ("CFCA"), once one person brings a CFCA action, "no other person may bring a related action based on the facts underlying the pending action." Cal. Gov't Code § 12652(c)(10). Relator Ven-A-Care of the Florida Keys filed a CFCA suit against Baxter in July 1998. *See* State of California's First Amended Complaint in Intervention, MDL 1456, Docket No. 1679 (Aug. 25, 2005) ¶ 23 ("This case was originally filed under seal July 28, 1998."). The State of California subsequently intervened in the suit, and Baxter settled this case in December 2008. *See* Exhibit Q at 12. The release covered all drugs manufactured under the Baxter labeler codes. *Id.*, Preamble, ¶ B and Exhibit A. Thus, Relators' claims are barred under both the "first to file" rule and the doctrine of accord and satisfaction.

2. Hawaii (Count IX)

The State of Hawaii filed an AWP complaint against Baxter, including Hawaii False Claims Act counts, on April 27, 2006. Exhibit R (Settlement Agreement and Release) § II(B). Baxter settled this case in March 2009. *Id.* at 8. Relators' claims here are covered by this Settlement Agreement and Release. *Id.* ¶ II, 6.

3. Illinois (Count X)

Under the Illinois Whistleblower Reward and Protection Act ("IWRPA"), a relator may not file a case "based upon allegations or transactions" that are the subject of that State's own civil, criminal, or administrative case. 740 Ill. Comp. Stat. 175/4(e)(3). The State of

Illinois filed an AWP complaint against Baxter in February 2005, and this case included an IWRPA count. Exhibit S (Settlement Agreement and Release) § II(C). Baxter settled this case in January 2009. *Id.* at 10. The Settlement Agreement and Release covers Relators' claims here.

4. Nevada (Count XVI)

Under the Nevada False Claims Act, a relator may not file a case "based upon allegations or transactions" that are the subject of that State's own civil, criminal, or administrative case. Nev. Rev. Stat. § 357.080(3)(b). The State of Nevada filed its own AWP action in January 2002. Exhibit T (Settlement Agreement and Release) § II(A). The amended complaint included claims under Nevada's Medicaid fraud statute and Nevada's False Claims Act. *Id.* Baxter settled this case in August 2008. *Id.* at 10. The Settlement Agreement and Release bars Relators' claims in this case.

5. Texas (Count XII)

Relator Ven-A-Care of the Florida Keys filed an action in Texas under seal in March of 2000, in which the State intervened in May 2000. *See* Exhibit U (First Amended Petition of the State of Texas in *Texas ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Abbott Labs., Inc. et al.*, Case No. GV00461-A) at 2 (unnumbered introductory paragraph). The complaint alleged improprieties related to the submission of drug pricing information to the Texas Vendor Drug Program (Texas Medicaid), including claims under the Texas Medicaid Fraud Prevention Act. *Id.*; *see also* Exhibit V (Settlement Agreement and Release) § II(B). Baxter settled this case in June 2006. Exhibit V at 15. Under the Texas Medicaid Fraud Prevention Act, no person other than the State may bring an action based on the same facts as an existing action. Tex. Hum. Res. Code Ann. § 36.106. Relators' claims here are barred as duplicative of the prior action. Moreover, pursuant to the settlement agreement, Baxter obtained a release from any future suit. Exhibit V § III, 3 (page 6). This release binds Relators here.

III. RELATORS CANNOT ASSERT A CLAIM FOR STARK ACT VIOLATIONS AGAINST BAXTER.

The Stark Act claim (Count II) must be dismissed under Fed. R. Civ. P. 12(b)(1) and/or Fed. R. Civ. P. 12(b)(6). *Qui tam* relators do not have standing to bring Stark Act claims:

> As for defendants' argument regarding relator's Stark Law claim, we agree with defendants that relator does not have standing to pursue a claim for a violation of the Stark Law. . . . . The Stark Law simply does not contain [a *qui tam*] provision. . . . [T]here has not been a partial assignment of the government's damages in a Stark Law claim to a relator. . . . Finally, we note that relator has not cited any cases in which a relator has been permitted to pursue a Stark Law claim in connection with an FCA claim.

United States ex rel. Repko v. Guthrie Clinic P.C., 557 F. Supp. 2d 522, 529 (M.D. Pa. 2008).

Relators also cannot state a cause of action for violation of the Stark Act by Baxter because the Stark Act applies only to physicians and other health care providers. 42 U.S.C. § 1395nn; *see United States ex rel. Roberts v. Aging Care Home Health, Inc.*, No. 02-2199, 2008 WL 2945946, at *8 (W.D. La. July 25, 2008) (determining that only physicians and home health agencies can violate the Stark Act and vacating the court's prior rulings that found otherwise). The Stark Act prohibits a physician (or family member of the physician) from receiving a kickback for referring patients to laboratories or other facilities in which the physician or family member of the physician has a financial interest. 42 U.S.C. § 1395nn. Relators allege that Baxter violated the Stark Act by providing discounts to institutional providers under Volume Committed Contracts. Complaint ¶¶ 52, 78. Because Baxter is not a physician or health care provider, and because this claims does not fit the Stark Act paradigm, this claim (Count II) must be dismissed.

CONCLUSION

Relators filed this lawsuit long after the FCA allegations made in the Complaint were publicly disclosed. They are not original sources and have not pled with requisite particularity.

The Pricing Scheme FCA counts of the Complaint (Counts I and III) thus must be dismissed, as must the corresponding State claims (Counts VII-XXI). Count II, the Stark Act claim, is inadequately pled and not appropriately asserted by Relators against Baxter. The remaining employment law claims have no relationship to the AWP litigation and should be sent back to the transferee court.

Respectfully submitted,

Dated: August 14, 2009

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CERTIFICATE OF SERVICE

I hereby certify that I, Ruchi Jain, an attorney, electronically filed the foregoing MEMORANDUM IN SUPPORT OF BAXTER INTERNATIONAL INC.'S MOTION TO DISMISS RELATORS' COMPLAINT with the Clerk of the Court for the District of Massachusetts using the Court's CM/ECF system on August 14, 2009. I also caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, for posting and notification to all parties. In addition, the individuals listed below were served a courtesy copy via U.S. Mail.

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